

REMARKS

In the subject Office action of 22 August 2006, claims 1-13 were examined. In response thereto, Applicants have amended claims 1, 6-8, 11 and 13, canceled claims 2-5, 9 and 10, added new claims 14-20, and left claim 12 under active prosecution in the present application. Applicants respectfully assert that all amendments are supported by the original disclosure and do not introduce new matter. Moreover, Applicants further respectfully assert that the amendments merely clarify the scope of the claims.

In the subject Office Action dated August 22, 2006, the drawings were objected to under 37 CFR 1.83(a) for failing to show the features of connecting member couplings and the band at the midpoint as referenced in the pending claims. In response thereto, FIG. 1 has been amended to add the component numbering "20, 22 and 24" for the couplings as support in the originally filed specification paragraphs [0032] and [0033]. FIG. 8 has been amended to add component numerals "114" and "116" and FIG. 10 has been amended to add the component numeral "114" as supported in originally filed specification paragraphs [0044]-[0045]. In addition, a new FIG. 13 has been added in compliance with 37 CFR 1.121(d), as supported by originally filed specification paragraph [0051], now [0052] that is amended to address this figure as follows: "anastomosis ring device 10a may include a circular fixture or band 20a at its midpoint for attaching the arcuate members that remains part of the anastomosis ring device 10a, intended to sit at a tissue juncture of the anastomosis." Applicants assert that one of ordinary skill in the art given the benefit of the originally filed disclosure would depict the circular fixture or band in an essentially identical fashion and thus no new subject matter has been added by the submission of this new figure.

Claim 13 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reciting the limitations "the applier, the actuating member and the distal ring" in line 4. The inadvertently included last line has been deleted by amendment to obviate the rejection. Reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1, 2 and 10 were rejected under 35 U.S.C. 102(e) as being anticipated by Park et al. (US 2003/0120292). Claims 9 was rejected under 35 U.S.C. 102(e) as being anticipated by Suyker et al. (US 6485496). Claims 3-7 and 11-13 were rejected under 35 U.S.C. 103(a) as being unpatentable over Park in view of Vesely (US 6569196) and further as a matter of design choice. Claims 1, 3 and 8 were rejected under 35 U.S.C. 103(a) as being unpatentable over Evard (US 6616675) in view of Park.

Turning to independent claim 1, the claim as amended incorporates the subject matter of dependent claim 5, by reciting in part an anastomosis device having legs of arcuate members of a first plurality attached to a respective arcuate member of a second plurality by a rigid connecting member. A petal formed by the first arcuate member actuates generally in a plane with the respective attached arcuate members pivoting about a cylindrical midpoint of the anastomosis device. A woven tube thus formed is operably configured to transform into a second position comprising a hollow rivet shape with each arcuate member outwardly deflected from a longitudinal axis of its respective cylindrical crown toward apposing arcuate members of the other cylindrical crown.

Claim 5 was rejected in the subject Office action as unpatentable over Park in view of Vesely. In particular, the Examiner relied upon Park to teach:

... an anastomosis ring device, comprising a plurality of arcuate members (20') operably configured to be arranged into two crowns attached to one another to present petal circumferentially hinged at a circular midpoint (from fig. 2 to fig. 3a), each arcuate member comprising a pair of diverging connected legs (18) ... and further teaches a petal formed by the first arcuate member actuating generally in a plane with the respective attached arcuate members pivoting about a cylindrical midpoint of the anastomosis device and wherein Park fails to teach the method of forming the device further comprising a pin and recess hinge along the midline of the device. Vesely teaches a medical implant wherein the members of the annular device are coupled by rigid pin hinges in order to ensure flexibility between the connected adjacent segments.

First, Applicants assert that a prima facie case of nonobviousness for claim 1 as amended has not been made as required by MPEP 706 "Rejection of Claims", citing 37 CFR 1.104(c)(2). First, modifications to the anastomosis device of Park that are taught by Vesely were not specifically identified. To the extent that the Applicant understands the rejection, Applicant asserts that the cited references as combined do not realize all of the limitations of the claimed invention. In addition, a motivation to modify the anastomosis device of Park has not been provided. In particular, the woven wire cylinder of Park bends when warmed due to the Shaped Metal Effect to a hollow rivet shape. Due to the deformable nature of the metal wires, no need exists to cause actuation about a hinged center portion. Reconsideration and allowance of claim 1, as well as claims 6-8 that depend therefrom is requested.

Claim 11, which has been revised into independent form, recites in part an anastomosis ring device, comprising a plurality of arcuate members operably configured to be arranged into two crowns attached to one another to present petals circumferentially hinged at a circular midpoint, each arcuate member comprising a pair of diverging connected legs wherein the first end of a first arcuate member pivotally connects to a second end of a second arcuate member and the second end of the first arcuate member connects to a first end of a third arcuate member.

Claim 11 was rejected on the same basis as claim 5 as discussed above regarding claim 1. For the same reasons, claim 11 should be reconsidered and allowed, as well as claims 12-13 that depend therefrom.

New claims 14-21 have been added that are originally filed apparatus claims 1 -8 rewritten into method of manufacture form, emphasizing a novel assembly and fabrication over the generally known woven anastomotic ring devices.

Regarding Claim 1, Park teaches an anastomosis device, comprising: a first plurality of arcuate members (first end of device 10) arranged in a first position in a cylindrical crown shape with each arcuate member having legs overlapping at least one adjacent arcuate member; and a second plurality of arcuate members arranged in a first position in an inverted cylindrical crown shape with each arcuate member having legs overlapping at least one adjacent arcuate member of the second plurality (second end of device 10) and connected (it is noted that Park is silent as to the method of making the device however, the term connected is broad and may encompass

portions integrally formed) to a leg of an arcuate member of the first plurality (Fig. 2); wherein the woven tube thus formed is operably configured to transform into a second position comprising a hollow rivet shape (Fig. 1) with each arcuate member outwardly deflected from a longitudinal axis of its respective cylindrical crown toward apposing arcuate members of the other cylindrical crown.

Regarding Claim 2, Park teaches the anastomosis device of claim 1, wherein the arcuate members comprise a shape memory effect alloy (Paragraph 32).

Regarding Claim 10, Park teaches an anastomosis ring device, comprising a plurality of arcuate members (20') operably configured to be arranged into two crowns attached to one another to present petals circumferentially hinged at a circular midpoint (from Fig. 2 to Fig. 3a), each arcuate member comprising a pair of diverging connected legs (18).

Claims 9 is rejected under 35 U.S.C. 102(e) as being anticipated by Suyker et al. (US 6485496).

Suyker teaches an anastomosis ring device, comprising: a means for forming a half cylinder (2) which actuates into a first apposing member about a midpoint at an anastomosis tissue juncture; and a means for forming an inverted half cylinder (3) which actuates into a second apposing member at the midpoint at the anastomosis tissue juncture (Fig. 3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Determining the scope and contents of the prior art.

Ascertaining the differences between the prior art and the claims at issue.

Resolving the level of ordinary skill in the pertinent art.

Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-7 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Park in view of Vesely (US 6569196) and further as a matter of design choice.

Park teaches all limitations of preceding dependent claim 10, and further teaches a petal formed by the first arcuate member actuating generally in a plane with the respective attached arcuate members pivoting about a cylindrical midpoint of the anastomosis device and wherein Park fails to teach the method of forming the device further comprising a pin and recess hinge along the midline of the device. Vesely teaches a medical implant wherein the members of the annular device are coupled by rigid pin hinges in order to ensure flexibility between the connected adjacent segments. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Park with pin and recess hinges along the midline in order to ensure flexibility between the connected adjacent segments.

The combination of Park and Vesely teaches a pin and recess hinge as described above, but fails to teach connecting members comprising a selected one of a group consisting of a snap fit, a glue, an ultrasonically welded portion, and a thermally melted polymer. It would have been an obvious matter of design choice to provide the combination of Park and Vesely with one of these connection members since such connections are well known in the art and it would be obvious to substitute the connection of the combination of Park and Vesely with another connection since it appears that the combination of Park and Vesely performs the task of ensuring flexibility between the connected adjacent segments equally well as that of the disclosed application.

Claims 1, 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evard (US 6,616,675) in view of Park.

Evard teaches an anastomosis device, comprising the following:

a first plurality of arcuate members (20) arranged in a first position in a cylindrical crown shape; a second plurality of arcuate members (20) arranged in a first position in an inverted cylindrical crown shape and connected (via portion 36) a leg of an arcuate member of the first plurality (fig. 4'); wherein the woven tube thus formed is operably configured to transform into a second position comprising a hollow rivet shape (fig. 4'') with each arcuate member outwardly deflected from a longitudinal axis of its respective cylindrical crown toward apposing arcuate members of the other cylindrical crown (fig. 4'').

Wherein the legs are attached to each other by a connecting member (36).

Wherein the connecting member comprises a band (36) at the midpoint of the device and connected to each arcuate member.

Evard fails to teach with each arcuate member having legs overlapping at least one adjacent arcuate member. Park teaches an anastomosis device wherein the legs of the arcuate members overlap in order to provide more coverage on the vessel wall. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Evard with overlapping legs as taught by Park in order to provide more coverage on the vessel wall.

CONCLUSION

In light of the amendments and remarks made herein, it is respectfully submitted that the claims currently pending in the present application are in form for allowance. Accordingly, reconsideration of those claims, as amended herein, is earnestly solicited. Applicants encourage the Examiner to contact their representative, David Franklin at (513) 651-6856 or dfranklin@fbtlaw.com.

No fees are due as after amendment, the claims total 14 with 3 independent claims. However, the Commissioner for Patents is hereby authorized to charge any deficiency or credit any overpayment of fees to Frost Brown Todd LLC Deposit Account No. 06-2226.

<p align="center">CERTIFICATE OF MAILING</p> <p>I hereby certify that a copy of this correspondence is being deposited with the US Patent Office by electronic transmission addressed to MS Amendment, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on</p> <p align="center"><u>November 17, 2006</u></p> <p align="center"><i>Elizabeth A. Middleton</i></p> <p>Elizabeth A. Middleton</p>

Respectfully submitted,

Jean Beaupre

By *David E. Franklin*

David E. Franklin
Registration No. 39,194
Attorney for Applicant(s)
FROST BROWN TODD LLC
2200 PNC Center
201 East Fifth Street
Cincinnati, Ohio 45202
(513) 651-6856
dfranklin@fbtlaw.com